

In accordance with 37 C.F.R. § 1.121, a marked-up version of claim 1 is provided on a separate sheet at the end of this reply.

### **REMARKS**

Applicants appreciate and acknowledge Director John Doll's grant of the Petition under 37 C.F.R. § 1.1981, to withdraw the finality of the Office Action of May 31, 2001.

Claims 1-21 are pending in the application for reconsideration. Claim 1 is further amended to clearly set forth the nature of the claimed invention. The amendment raises no new issues requiring further consideration and/or search and does not add matter that is unsupported by the specification. Accordingly, Applicants earnestly solicit entry of the amendment.

#### ***Rejection Under 37 C.F.R. § 102(b)***

The Examiner alleges that claims 1-2, 4-5, 9-13, and 16-20 are anticipated by Cingotti (U.S. patent No. 5,427, 800) on the ground that "Cingotti meets the limitations of the instant claims."

In the Office Action, the Examiner stated that "Cingotti's sorbitol microgranules are analogous to the instant neutral core and possess the same particle size." Applicants respectfully disagree with the Examiner's statement for the following reasons.

Firstly, Cingotti's sorbitol microgranules are "nebulized porous excipient microgranules," obtained by a "spray drying process" by means of a "nebulizer," also known as an "atomizer" or as a "spray drier." In addition, Cingotti's sorbitol microgranules present "a multitude of superficial cavities and internal ducts, i.e. small radial ducts that point towards the interior of the granules" (see column 2, line 57 to column 3, line 1).

The neutral pellets used in the present invention cannot be considered analogous to Cingotti's microgranules. It is well known that neutral pellets are dense and unified and possess a homogeneous structure. By contrast, Cingotti's microgranules are highly porous and not homogeneous. For this very reason, Cingotti

did not refer to the sorbitol microgranules as "neutral cores" or "neutral pellets." Thus, the term "nebulized" was frequently used all through out the specification (see column 2, lines 60-68; column 3, lines 22-28 and 33-38; column 3, line 61 to column 4, line 4).

Secondly, according to Cingotti, the silica granules, coated with the dry extract, are "adsorbed in" and "on nebulized porous sorbitol microgranules" as "carrier(s)" (see column 2, lines 57-60, column 3, lines 4-8). Again, Cingotti emphasizes this characteristic (see column 3, lines 24-25) by stating that "it is important that this carrier has a strong adsorption capacity to retain the active substances" (column 3, lines 34-36). This is evidenced by the fact that the cavities and ducts are filled with granules. On the contrary, according to the present invention, the plant extract is directly deposited on the neutral core by being combined with a pharmaceutically acceptable excipient rather than being carried by a silica granule having a particle size of 18 nanometers, as described by Cingotti (column 3, line 52).

Thirdly, Cingotti's direct impregnation of the sorbitol microgranules without the intermediary step of involving silica granules "rapidly" results to "a congealed mass" that is not "homogeneous" and "impossible to dry and gauge" (see column 5, lines 12-17). As discussed earlier, according to the claimed invention, plant substances are homogeneously, uniformly and reproducibly coated in microgranules comprising a neutral core.

Lastly, whereas Applicants' invention involves coating of the active substance by spraying (see specification, at page 6, lines 1-10), Cingotti's invention involves adsorbing of silica granules carrying extracts onto the nebulized porous sorbitol microgranules by mixing and agitating (column 4, lines 10-11).

Because Cingotti fails to teach each and every element of the claimed invention, this reference cannot be anticipatory. All of the rejected claims are dependent on claims 1 and 11. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the above rejection under section 102.

***Rejection Under 37 C.F.R. § 103(a)***

The Examiner alleges that claims 3, 6-8, 14-15, and 21 are unpatentable over Cingotti (see above) and Menzi *et al.* (U.S. patent No. 6,056,949), in view of Breitenbach *et al.* (U.S. patent No. 6,120,802). Applicants respectfully traverse this rejection.

At the outset, the Examiner has failed to establish a *prima facie* case of obviousness with respect to the claimed invention. He must show all of the recited claim elements in the combination of references that underscore the rejection. When combining elements to make out a *prima facie* case of obviousness, that is, the Examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make the combination and (ii) a reasonable expectation that the combination would succeed. Both suggestion and reasonable expectation must be found within the prior art, and not be gleaned from Applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1531 (Fed Cir. 1988).

The above-mentioned arguments presented to overcome the rejections over Cingotti are herein incorporated by reference in their entirety.

The Examiner relies on Menzi for its suggestion to use flavorants and odorants comprising plant extracts. More specifically, Menzi teaches the process for manufacturing spherical particles granulated with an emulsion, that is sprayed into the cores. Menzi teaches a process "characterized by spraying a flavorant or odorant emulsion *into* a core material." As shown in Figure 1 of the '949 patent, the encapsulated flavorant (3) is at the same time around and in the nucleus cores (2). The flavor and odor producing substances of Menzi represent active core ingredients. By contrast, the present invention relates to the use of neutral core to carry the plant substance. Accordingly, Menzi does not make up for the deficiencies of Cingotti by itself or in combination, to enable one of ordinary skill in the art to make and practice the claimed invention.

The Examiner relies on Breitenbach for its suggestion to use plasticizers and binders but the Examiner admits that it does not teach the use of a neutral core. In fact, Breitenbach specifically teaches a process comprising a coextrusion step which

necessitates the use of a thermoplastic polymeric binder. By contrast, the claimed microgranules are prepared according to coating techniques, preferably in a pan or in a fluidized air bed (page 6, lines 30-32 of the specification). A binder may be used if the coating is performed by spraying (page 6, lines 7-10 of the specification). In this regard, Breitenbach fails to correct the deficiencies of the combined teachings of Cingotti and Menzi, neither of which teach or suggest the claimed neutral core, for the above-mentioned reasons.

Accordingly, the Examiner has failed to make a case of *prima facie* obviousness, and as a result of these deficiencies, it is respectfully requested that the above rejection be withdrawn.

### CONCLUSION

In view of the foregoing, it is respectfully urged that the present claims are in condition for allowance. An early notice to this effect is earnestly solicited. If any additional extensions of time are needed for the filing of this paper, Applicants expressly petition for such extensions and authorize the Commissioner to charge any deficiency to Deposit Account 19-0741.

Should there be any questions regarding this application, especially if the Examiner feels that he would benefit from further clarification of the invention, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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**MARKED UP VERSION SHOWING CHANGES MADE**

**In the Claims:**

1. (Thrice Amended) Granules containing at least one plant substance, comprising a neutral core having a particle size of between 200 and 1600  $\mu\text{m}$  coated with a layer [consisting of] containing the plant substance combined with a pharmaceutically acceptable excipient.